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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/835,537

04/16/2001

Carl R. Merrill

PNC-004

5407

7590

07/27/2006

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/835,537

Applicant(s)

MERRIL ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 19 and 21-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 19,21-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

- I. Rejection of claims 19,21-35 under 35 USC 112, 1<sup>st</sup> paragraph with respect to "guanidine acetate" and rejections of claims 19,22-25,27-29 under 35 USC 102(e) and 103 (a) as being anticipated by / obvious over Kaddurah-Daouk will be maintained for reason on record and reason as follows in light of amendment filed 5/10/06. Applicant provides a structure of Guanidinoacetate and states that Guanidinoacetate differs structurally from Guanidine acetate. However, Applicant does not provide a structure of Guanidine acetate to show that it is not structurally equivalent to Guanidinoacetate.
- II. Rejection of claims 19, 21-35 under 35 USC 112, 1<sup>st</sup> paragraph with respect to guanidine salt and prion diseases will not be maintained in light of amendment filed 12/19/05. Examiner withdraws this rejection since generally in the art is acceptable to use various salt forms of actives and because specification is clear to what prion diseases are of interest.
- III. Rejection of claims 19,20,23, and 24 under 35 USC 102(b) as being anticipated by Goldin will not be maintained in light of amendment filed 12/19/05. Fatal familial insomnia is a genetic disease of a prion protein abnormality, whereas insomnia is not associated with a prion protein abnormality.
- IV. New Rejections

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 30,32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 32 are rejected. It is unclear as to what is being administered. However, Examiner is interpreting claims 30 and 32 as to mean the administering of guanidine HCl and KI respectively.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19,23-29,31 are rejected under 35 U.S.C. 102(b) as being anticipated by Azumendi (GB 2315672; 2/11/98). Azumendi teaches a method of treating prion disease (BSE, CJD) in mammals (human, cow, horse) comprising administering an effective amount of NaI or KI (chaotropic agents) to the mammals. It is inherent that hyperthermia in mammals would be induced by the KI or NaI at the time the invention was made since the prior art and the instant method teach the same step of administering NaI or KI to the mammal.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azumendi as applied to claims 19,23-29,31 above. See 35 USC 102(b) rejection above. Azumendi teaches all that is recited in claim 32 except for the administering between 130 and 260 mg per kg per day. It is unclear as to what is being administered. However, Examiner is interpreting the claim as to mean the administering of KI. If this is so, Azumendi is silent to the dosage of KI to be administered per kg per day. However, it would have been obvious to one having ordinary skill in the art to determine the optimum dosage through routine experimentation. Since the reference is silent to the dosage, Applicant must show the criticality of the instant dose range.

#### ***Claim Objection***

Claim 23 is objected to for depending from cancelled claim 1. Correction is necessary.

Claim 27 is objected to. Insert --- or --- after CJD in line 2 of claim 27.

Claims 21,33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the instant invention guanidine HCl, microwave energy, and pyrogenic material.


#### ***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Alton Pryor  
Primary Examiner  
AU 1616